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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,406	02/25/2004	Piotr Topilko	BJS-3665-90	9802

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,406	TOPILKO ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *14-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

☒ Notice of References Cited (PTO-892)

☐ Draftsperson's Patent Drawing Review (PTO-948)

☐ Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I claims 1-13 in the reply filed on 11/13/2006 is acknowledged. The traversal is on the ground(s) that a search and examination of all of the claimed subject matter is not believed to place an undue burden on the Examiner. This is not found persuasive because a search burden would be placed upon the Examiner to search all of the compounds and markers that are in claims 14-21 which comprise Groups II and III.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/13/2006.

3. Claims 1-13 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing mouse neural pluripotent cell comprising the ex

vivo culture or in vitro culture of mouse Boundary Cap (BC) cells, a pharmaceutical composition comprising mouse BC cells, a method of tissue re-engineering in a mouse comprising administering to a mouse a suitable amount of mouse BC cells and a method of treating, reducing or alleviating pain in a mouse, does not reasonably provide enablement for a method of producing neural pluripotent stem cell from any mammalian BC cell, a pharmaceutical composition comprising any mammalian BC cell, a method of tissue re-engineering in any subject, and a method of treating, reducing or alleviating pain in any subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-13 are drawn to a method of producing neural pluripotent cell by culturing mammalian BC cells, a pharmaceutical composition comprising BC cells, a method of tissue re-engineering using BC cells, and a method of treating, reducing or alleviating pain in a subject using BC cell administration.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737,

8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claims encompass making and using neural pluripotent cells from any mammalian BC cell.

However, the art teaches that such a method would be unpredictable. It is of significant note that the specification teaches on page 2 lines 15-22 that only mouse BC cells can 1) be identified and 2) be cultured into neural pluripotent cells. The reasons for this, as the specification teaches, is because only one BC mouse-specific marker, Krox20, has been identified to identify BC cells. This limitation alone, results in the scope of the instant claims to mouse BC cells. Similarly, the specification teaches that little is known about BC cells (pg. 2 lines 30-31) in general and the art of record supports this (Neiderlander et al., 1996, Development, Vol. 122, pgs. 2367-2374). However, the instant specification and claims are centered around the discovery of mouse BC cells differentiating into neural pluripotent cells and their applied uses.

The working examples in the instant specification on pages 19-26 teach the identification of mouse BC cells using Knox20 knock-in mouse embryos, and that further these cells develop into neural pluripotent cells. However, because of the limitations of identifying any mammalian BC cell, as discussed above the limitation to only mouse BC cells is therefore limitation of the claims. The instant specification does not teach any other markers or means of identifying any

other mammalian BC cell other than mouse. Thus the skilled artisan would require and undo amount of experimentation without a predictable degree of success to make and use the invention as claimed. Thus the scope of the claims being limited to a method of producing mouse neural pluripotent cell comprising the ex vivo culture or in vitro culture of mouse Boundary Cap (BC) cells, a pharmaceutical composition comprising mouse BC cells, a method of tissue re-engineering in a mouse comprising administering to a mouse a suitable amount of mouse BC cells and a method of treating, reducing or alleviating pain in a mouse is proper.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Deborah Crouch

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